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SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-0011-14T2

LINDA GROSS and JEFFREY GROSS,

Plaintiffs-Respondents,

v.

GYNECARE,

Defendant,

and

ETHICON, INC., and
JOHNSON & JOHNSON,

Defendants-Appellants.

Argued February 23, 2016 – Decided March 29, 2016

Before Judges Fisher, Espinosa and Rothstadt.

On appeal from the Superior Court of New Jersey, Law Division, Atlantic County, Docket No. L-6966-10.

Charles Lifland (O'Melveny & Myers LLP) of the California bar, admitted pro hac vice, argued the cause for appellant (Riker, Danzig, Scherer, Hyland & Perretti, LLP, and Mr. Lifland, attorneys; Mr. Lifland, of counsel; Kelly S. Crawford, Christy D. Jones (Butler Snow) of the Mississippi bar, admitted pro hac vice, and William M. Gage (Butler Snow) of the Mississippi bar, admitted pro hac vice, of counsel and on the brief).

Adam M. Slater argued the cause for respondents (Mazie Slater Katz & Freeman, LLC, attorneys; Mr. Slater and David A. Mazie, of counsel; Mr. Slater, Mr. Mazie and David M. Estes, on the brief).

PER CURIAM

This appeal requires our consideration of the Prolift Pelvic Floor Repair System (Prolift), a transvaginal surgical mesh designed, manufactured and marketed by defendants Gynecare, Ethicon, Inc., and Johnson & Johnson to treat pelvic organ prolapse and stress urinary incontinence. Plaintiffs Linda and Jeffrey Gross, residents of South Dakota, commenced suit here, alleging that, as a result of the implantation of this medical device, Linda sustained multiple complications and required intensive medical treatment and numerous operations. After a lengthy trial, the jury found in favor of defendants on the claims of defective design and fraudulent misrepresentation to the implanting surgeon but found in favor of plaintiffs on their claims of failure to provide adequate warnings to the implanting surgeon, fraudulent misrepresentation to plaintiff, and loss of consortium, and awarded $3.35 million in compensatory damages. After additional proceedings, the jury awarded $7.76 million in punitive damages.

In appealing, defendants argue the trial judge: erroneously failed to apply the learned intermediary doctrine to the fraudulent misrepresentation or deceit claim; misapplied that doctrine to the

failure-to-warn claim; should have recognized the causation evidence was insufficient to prove a failure to warn; made erroneous evidence rulings; and mistakenly allowed the jury to consider punitive damages.

We affirm.

I

On November 3, 2008, plaintiffs filed their complaint against defendants Johnson & Johnson (J&J), Ethicon, Inc., and Gynecare. The matter was assigned, along with all future pelvic mesh state court litigation, to Atlantic County for centralized management.[1]

Prior to trial, the judge considered numerous in limine motions and, among other things, denied in part and granted in part defendants' motion to exclude evidence and argument concerning post-implant events after July 13, 2006, the date plaintiff underwent implant surgery. The judge also denied without prejudice motions relating to the May 15, 2008 decision of the Food and Drug Administration (FDA) to grant clearance of Prolift under 501(k) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C.A. § 360, and the learned intermediary doctrine; the judge concluded such arguments could be re-asserted at trial, if

[1] We are told this is the first (and to date only) case to be tried in the New Jersey coordinated proceeding for cases alleging personal injuries from Ethicon's pelvic mesh products.

warranted.

The trial took place between January 7 and February 25, 2013. At the outset, the parties stipulated South Dakota law would apply to the substantive issues, but New Jersey law and rules would govern procedural issues and the punitive damages claim.

Plaintiffs rested on February 5, 2013, and defendants unsuccessfully moved for judgment as a matter of law as to all claims. After they rested a week later, defendants renewed their motion, and the judge reserved decision. Plaintiffs also moved for a directed verdict on all claims; the judge denied that motion.

The jury returned its verdict on February 25, 2013, finding: (1) Prolift was not defectively designed; (2) defendants did not provide adequate warnings to the implanting surgeon; (3) defendants' failure to provide adequate warnings was a proximate cause of plaintiff's injuries; (4) defendants did not make a fraudulent misrepresentation to plaintiff's implanting surgeon; (5) defendants made a fraudulent misrepresentation to plaintiff; and (6) defendants' fraudulent misrepresentation to plaintiff was a proximate cause of her injuries. The jury awarded plaintiffs $3.35 million in compensatory damages. Following the verdict, defendants moved for judgment notwithstanding the verdict (JNOV); the judge reserved decision.

The punitive damages phase commenced the next day. After

plaintiffs rested, the judge denied defendants' motion for judgment and, on February 28, 2013, the jury awarded $7.76 million in punitive damages. Final judgment was entered on July 2, 2013.

Defendants had, in the meantime, renewed their motions for JNOV and, alternatively, for a new trial or remittitur. On July 15, 2014, the judge denied defendants' motions.

Defendants Ethicon and J&J timely filed a notice of appeal.

II

Because many of the issues raised are fact-sensitive, we explain at some length the evidence adduced at trial regarding (a) pelvic organ prolapse, (b) the development of Prolift, and (c) plaintiffs' surgeries and treatment.

A

Pelvic organ prolapse occurs when pelvic floor muscles become weak or dysfunctional and cease supporting the organs in the pelvic area, causing connective tissue attachments to stretch or break and organs to become displaced. A prolapse may occur in many ways, i.e., when: the bladder drops (cystocele); the rectum protrudes upwards (rectocele); the small bowel pushes the vagina toward the opening (enterocele); the uterus comes down into the vagina (uterine prolapse); or, for women with hysterectomies, the top of the vagina pushes into the lower vagina (vaginal vault prolapse). Potential contributing causes of pelvic organ prolapse

include age, multiple vaginal deliveries, obesity, pelvic trauma, prior surgery, and loss of muscle tone. Serious cases may lead to urinary and bowel incontinence, impaired sexual function, bladder infections, sensations of pelvic heaviness, and bulging tissue. Pelvic organ prolapse affects approximately one in three women over forty-five years of age.

Non-surgical treatments to manage prolapse include the use of a pessary device inside the vagina to help support the pelvic area and Kegel exercises to contract and relax the pelvic floor muscles. One surgical option involves traditional native tissue repair or colporrhaphy, in which weakened vaginal tissue is cut and stitched to other supporting tissue; this procedure produces a high rate of recurrence. Another option, in use since the 1960s, involves surgical implantation of synthetic meshes through the abdomen, also known as abdominal sacrocolpopexy, which achieves higher cure rates than native tissue repair; in such instances, however, the abdominal incisions involve significant complications and risks, as well as long recovery times.

B

In 2002, Ethicon began to market Gynemesh PS to treat pelvic organ prolapse. Gynemesh PS used the same polypropylene mesh previously marketed as Prolene Soft, which had been used in hernia repairs, to allow the ingrowth of tissue and to stabilize fascial

structures in the pelvic floor. This mesh was sold in flat rectangular sheets of two different sizes that a surgeon could cut into the appropriate shape and then stitch into place. Ethicon designed Gynemesh in two sizes for vaginal and abdominal approaches; it did not provide tools for insertion.

On January 8, 2002, Ethicon received 510(k) clearance[2] from the FDA for the use of Gynemesh PS in the pelvic floor. Unlike a request for premarket approval of a product with no known predicate, as a general matter 510(k) clearance does not require clinical trials but requires the company to compare its product to one already on the market, in this case Prolene Soft. The FDA then reviews the information to determine if the new device is as safe and effective as the predicate. When obtaining clearance, a company obligates itself to comply with the FDA's post-marketing requirements to track any complaints or adverse events and to report any serious or life-threatening injuries.

Meanwhile, in 2000, a group of gynecological surgeons in France began an exploratory program to develop a transvaginal mesh (TVM) procedure to treat pelvic organ prolapse. In seeking to

[2] 510(k) clearance is a premarket notification that the new device was "substantially equivalent" to an existing device or "predicate" already approved. 21 C.F.R. 807.87. The FDA relies on the manufacturer to determine when modifications to a device raise new issues of safety and effectiveness, and to provide the appropriate documentation.

develop a standardized technique to surgically repair prolapses and better understand mesh-related complications, the French TVM group worked with Ethicon and its Gynecare division, which coordinated the group's logistics.

In developing a technique to surgically implant mesh through the vagina, the French surgeons sought a soft mesh product that would resist infection as much as possible, incorporate the surrounding tissue, resist shrinkage, and limit fibrosis or scarring; they selected the same mesh material as Gynemesh PS and designed a system to insert the mesh in the pelvic area. This approach consisted of a pre-cut mesh implant and the instruments needed to perform a vaginal repair, which incorporated a large central implant with six straps or "arms" – four straps secured the anterior portion of the implant between the bladder and the vagina and two secured the posterior portion between the rectum and the vagina. These straps extended into the hip, thigh, groin and buttocks, and were designed to become fully integrated into the body.

Prolift inserted a larger volume of mesh into the pelvic space than did Gynemesh PS. Also, unlike Gynemesh PS, the Prolift kit included single-use inserter instruments including a guide, cannula, and retrieval line. Referred to as a "cannula introducer device," the guide was used to create tissue paths for the

placement of the mesh implants and to facilitate placement of the cannula, which was a flexible white tube fitted over the guide and placed inside the patient "to facilitate passage of the implant straps while protecting the surrounding tissue." Once the cannula was held in place, the guide was removed. The retrieval device then guided the mesh strap through the cannula until the loop on its distal end captured the strap and drew it out through the cannula. According to Axel Arnaud, M.D., who "initiated and set up the [French] project,"[3] Prolift was designed to create a barrier to all potential defects in the pelvic floor and, while the mesh material was the same as Gynemesh PS, the size and the technique were "completely different."

In April 2003, Ethicon held a "kickoff meeting" for the Prolift exploratory project. Scott Ciarrocca, who became the research and development project leader, was responsible for design control activities and the accumulation of documents for the design history profile. His team performed design verification studies to test mesh thickness, tear strength, and dimensions. Ciarrocca considered Gynemesh PS the "state-of-the-art material at the time."

Ciarrocca's team also conducted a "design failure modes and

[3] Dr. Arnaud was the scientific director of Gynecare in Europe from 2001 to 2008.

effects analysis" (dFMEA), which focused on the design of the instruments. Additionally, his team performed an "application failure modes and effects analysis" (aFMEA) to determine how the instruments were used and potentially misused, and a "process failures modes and effects analysis" (pFMEA) to find ways to make the manufacturing process "robust" by ensuring that every time the components were made, "the same product [went] out the door." One of the last research and development activities was design validation to prove the design met the specifications. At that point, the team asked physicians who were uninvolved in the project development to perform simulated surgeries on cadavers using the Prolift kit; Ciarrocca's team was provided with feedback.

On July 19, 2003, Ciarrocca received an email from Professor Michel Cosson, an academic surgeon and member of the French TVM group, that identified problems with the mesh material including erosion (exposure through the vaginal wall or into organs), contraction (formation of scar tissue around the mesh, which pushes it together), and recurrence (the return of prolapse). Cosson wrote that if erosion or recurrence occurred due to the mesh, the team needed "to go back into the concept stage, delay launch and increase resources."

On October 6, 2004, Sean O'Bryan, who developed the regulatory strategy for Prolift at the project's inception, advised Ciarrocca

that FDA Guidelines did not require a new 510(k) premarket notification. He explained at trial that the differences between Gynemesh PS and Prolift were not significant enough to warrant a new 510(k) clearance.

In 2004, Ethicon prepared Prolift's "instructions for use" (IFU), which was written for the implanting surgeon and packaged with every Prolift kit. It advised physicians that the "[f]ailure to properly follow instructions may result in improper functioning of the devices and lead to injury," and that training was recommended and available. The IFU stated that the Prolift total, anterior or posterior pelvic floor repair systems were indicated for "tissue reinforcement and long-standing stabilization of fascial structures of the pelvic floor in vaginal wall prolapse." The IFU described the pre-cut Gynecare Gynemesh PS, noting it was approximately 50% more flexible than standard Prolene mesh. And it identified potential adverse reactions, including: "those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction"; other identified adverse reactions included "[p]unctures or lacerations of the vessels, nerves, bladder, urethra, and bowel" that might occur during guide passage and require surgical repair.

Charlotte Owens, M.D., who joined Ethicon as worldwide medical director in 2003 and left in August 2005, testified that she understood the document had to be clear, unambiguous, accurate, and supported by data, and she claimed the IFU communicated all contraindications, warnings, precautions, and adverse reactions to physicians. At trial, Owens could not recall any supporting data for the statement in the IFU that the bi-directional elastic property of Gynemesh PS allowed adaptation to various stresses encountered in the body. Owens acknowledged that she approved the IFU even though she knew there might be long-term complications.

Meanwhile, the French surgeons had been using the Prolift kit and following their patients over several years. In November 2004, they published an article addressing Gynemesh Soft, the same mesh material used in the Prolift system, opining that retraction was impossible to forecast and highly variable and that its "after effects" included dyspareunia (painful sexual intercourse).

On January 11, 2005, Arnaud, the scientific director of Gynecare Europe, sent an email to Ophelie Berthier, the product director who oversaw the marketing launch of Prolift worldwide, proposing to add the following warning to the IFU:

> Warning: Early clinical experience has shown that the use of mesh through a vaginal approach can occasionally/uncommonly lead to complications such as vaginal erosion and retraction, which can result in an anatomical

> distortion of the vaginal cavity that can interfere with sexual intercourse. Clinical data suggests the risk of such a complication is increased in cases of associated hysterectomy. This must be taken in consideration when the procedure is planned in a sexually active woman.

Berthier advised Ciarrocca it was "quite urgent" to incorporate the changes in the IFU version in the procedure CD-ROM.

Ciarrocca forwarded this email to O'Bryan and Owens, asking whether it was "okay to add such a sentence as it is being proposed without FDA approval." On January 13, 2005, O'Bryan responded: "We can change the adverse event to whatever is most appropriate without FDA implications. I will leave it to Charlotte [Owens] and Axel [Arnaud] to decide." O'Bryan noted that the IFU had already been approved through an internal process used to review important labels, and that it most likely had "gone out for translations," meaning it was in the hands of the printer. Ciarrocca replied:

> We have already printed launch stock. This would be a next revision addition, but they want it in there ASAP.

At trial, he acknowledged the proposed warning was not included in the first IFU because Ethicon did not want to reprint it, noting a motivation to get the product to market as soon as possible. The warning, however, did not appear in the next revision and only appeared in May 2008 after the FDA required more explicit language

about the risks related to sexual function, such as the possibility of "pain with intercourse."

On January 14, 2005, Owens issued a clinical expert report to document the "safety and functionality" of the Prolift system to treat pelvic floor repair. She relied on a Gynemesh PS clinical study that was ongoing when she arrived at Gynecare as the foundation from which to draw relevant information for her report. That study was performed by multiple physicians using Gynemesh PS for vaginal and abdominal placements; the Owens' report on Prolift listed the same potential complications identified in the Gynemesh PS study, such as "[i]nfection, mesh exposure, fistula, hematoma, and contraction." She reported there were no instances of tissue contraction in the Gynemesh clinical evaluation.

At the time she authored this clinical expert report, Owens was familiar with the 2004 article published by the French TVM group that identified retraction as a potential complication along with such after effects as dyspareunia and severe pain. Owens did not cite the article in her report or discuss the possibility of retraction.

Owens testified that surgeons were expected to inform their patients of potential risks associated with any pelvic floor repair, including uncomfortable sexual relations. She acknowledged Prolift represented the first time the mesh material was marketed

"in that shape, size, with those instruments, [and] with that accompanying procedure," and she also acknowledged she had only performed the Prolift implant in cadavers.

On February 8, 2005, Ciarrocca signed the last design validation report showing what Ethicon learned during validation of the instruments by physicians in the cadaver labs. The report was also signed by Owens and O'Bryan, among others. In response to a comment from a participating physician, Ethicon wrote: "Clearly, for most physicians, the Prolift procedure will be a deviation from what they are currently doing."

Noting that pelvic floor surgeries were complex and posed risks, Ciarrocca explained that "at the end of the day" Owens decided there was sufficient evidence that the benefit exceeded the risks. He explained that some risks could be mitigated by providing detailed educational materials for the surgeons and acknowledged that prior to the marketing of Prolift in March 2005 the Prolift instruments were never tested in a clinical study. Nevertheless, he maintained the mesh implants were tested in animal studies.

Owens testified that, before the market launch of Prolift, she knew the mesh could erode, migrate, or lead to inflammation and, also, that removal of mesh could be very difficult even though Ethicon did not conduct studies on how to remove it. She also

knew the guide process through the pelvis could damage the pudendal nerve, which innervates parts of a woman's pelvis that allow for normal urinary and bowel function. Owens admitted she was unaware of any unanticipated adverse events that occurred after Prolift's launch and before she left Ethicon.

Arnaud similarly testified that, prior to Prolift's launch, he was aware of such potential problems as erosion and retraction of mesh with potential risks of pain, dyspareunia, and prolapse recurrence. He was also conscious of the need to improve the mesh material to reduce stiffness in the area of the implant where scar tissue formed and shrinkage occurred. Arnaud admitted that, at the time, he did not understand the mechanism of erosion or know how to reduce mesh shrinkage. In his view, it was the surgeon's responsibility to develop solutions if a patient experienced complications.

Likewise, Piet Hinoul, M.D. — an urogynecologist[4] who joined Gynecare in 2008 as a worldwide medical director — confirmed that on the day of the launch Ethicon was aware of potential complications, such as urinary incontinence, urinary retention or obstruction, ureteral obstruction, voiding dysfunction, pain, pelvic pain, and pain with intercourse. Hinoul claimed all

[4] Urogynecology is a surgical specialty that treats mostly pelvic organ prolapse and urinary incontinence.

potential risks were listed in the IFU even if they were not identified by name, and he explained the first sentence in the IFU's warnings section stated that Prolift must be performed by doctors skilled in pelvic organ prolapse surgery and the use of synthetic meshes. According to Hinoul, pre-marketing tests showed Prolift had low complication rates comparable to other prolapse surgeries.

In March 2005, Ethicon began marketing Prolift to treat pelvic organ prolapse and stress urinary incontinence. Prolift was marketed in three kits: an anterior Prolift designed to provide support to the anterior vagina or "front half"; a posterior Prolift; and a total Prolift. At the time of launch, Ethicon had not conducted a clinical study on live people. The launch was accompanied by the IFU prepared in 2004 and the patient brochure. As described by Hinoul and David B. Robinson, M.D., the director of medical affairs at Ethicon from early November 2005 until the end of 2010, the purpose of the patient brochure was to facilitate discussions between the patient and her physician about the benefits and risks of the Prolift system. Hinoul explained that the implanting physician was expected to explain the Prolift system to the patient after which the patient could read the brochure and discuss any additional questions with her doctor. Robinson acknowledged a patient could be expected to rely on the patient

brochure — which he described as "an abbreviated instruction for use" — and consider its statements about the benefits and risks of the Prolift device as part of the decision-making process with the physician, and he recognized the brochure did not mention dyspareunia, a known potential adverse reaction.

The brochure promoted Prolift as "a revolutionary new minimally invasive surgical technique that offers promising long-term results for women with pelvic organ prolapse," advised patients that "[a]ll surgical procedures present some risks," and additionally observed that:

> Although rare, complications associated with the procedure include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury. There is also a small risk of the mesh material becoming exposed into the vaginal canal.

The patient brochure and IFU included the same warnings and precautions, and adverse reactions. Neither document mentioned the risks of repeated erosions, dyspareunia, the inability to remove mesh, pudendal neuralgia (an abnormality in the nerve fibers), or chronic pain. Nor did either mention that physicians should be highly skilled and experienced in performing pelvic floor repair surgeries. The brochure instructed the patient to "[t]alk with your doctor or healthcare provider about pelvic organ prolapse and what you can do about it" and cautioned that "[o]nly

a complete physical examination and consultation with your physician can determine which procedure is right for you."

On March 22, 2005, Cosson and other members of the French TVM group published an article discussing the results of a study of 277 patients eight weeks after Prolift surgery. They found that thirty-four patients experienced mesh exposure and, after a month of treatment, twenty-five required surgery. Based on this data, the authors advised that "caution be exercised when carrying out this new surgical procedure" and suggested "experimental studies and clinical trials . . . in order to reduce the level of exposure to less than 5% of cases."

In a November 23, 2005 email — eight months after Prolift went on the market — Arnaud wrote to several individuals at Ethicon about information he had received from Professor Jakob Eberhard, a Swiss surgeon who performed anterior Prolifts. Eberhard claimed, among other things, that: the insertion of the straps required too many steps, including the "placement of the cannula, insertion of the retrieval devices, [and] capture of the strap"; that a risk for vessel or bowel perforation was present because the guide was too sharp; and that after retrieval of the cannula, the straps took on a rope-like shape, instead of lying flat, causing some patients discomfort. Arnaud advised Ethicon to take Eberhard's remarks into consideration. Ethicon received other post-launch

reports from surgeons that patients complained of the inability to void following the procedure and of dyspareunia with pain at the six-arm insertion points.

On June 27, 2006 — a few weeks before plaintiff's implant surgery — the French TVM group published the results of its study of 106 patients to determine the recurrence of prolapse twelve months post-procedure. The results did not meet the pre-defined criteria of success, which defined a prolapse recurrent rate of less than twenty percent. Nonetheless, they concluded that the study demonstrated "reasonable success rates" and a recurrence rate that compared favorably "with re-operation rates of around 30% using traditional vaginal approaches in other studies."

On February 23, 2007, Cosson wrote that it might be possible to improve polypropylene mesh in terms of shrinkage and that a new material might be needed. In an email dated October 29, 2008, Jonathan Meek, worldwide marketing director for Ethicon, described polypropylene as "the best of a bad lot" with respect to integration and retraction, saying there was "a need to develop grafts that mimic the human tissue mechanical properties."

Meanwhile, as early as January 2005, Gene Kammerer, an engineer at Ethicon, suggested the possibility of using Ultrapro mesh for pelvic floor repair in place of Gynemesh. In an email dated April 13, 2005, he wrote that surgeons and customers wanted

a better mesh to reduce contraction and scar tissue and that Ultrapro would make the procedure better for patients and give Ethicon a significant advantage over the competition. Kammerer said Ultrapro had a lower inflammatory response, left behind less material than Prolene Soft, and had a larger pore size than Gynemesh PS to better allow the ingrowth of tissue.

Over the next four years, Ethicon developed Ultrapro mesh for pelvic floor repair, which it marketed as the Prolift+M Pelvic Floor Repair System (Prolift+M).

C

Plaintiff Linda Gross, a registered nurse, and her husband, Jeffrey, resided in Watertown, South Dakota, and had three children. Clark Wayne Likness, M.D., the family physician who delivered the children, testified plaintiff had an episiotomy and rectal tear after the first birth in 1985, an episiotomy after the second birth the following year, and a small superficial tear after the third birth in 1990, with no follow-up issues.

In 2001, plaintiff, then thirty-five years old, saw Kevin Benson, M.D., a urogynecologist and pelvic reconstructive surgeon, complaining of increased bleeding and frequency of menstrual periods and urinary incontinence. Benson performed an examination and found a Grade 2 cystocele — meaning the bladder protruded "[j]ust about to the opening" of the vagina. After discussing the

risks of various options including a pessary implant and birth control pills to treat her menstrual issues, plaintiff opted for surgery. Benson performed a vaginal hysterectomy to remove her uterus, a Burch urethropexy to treat her stress urinary incontinence, and a McCall's culdoplasty to provide apical support and prevent a future prolapse. Plaintiff suffered from post-spinal headaches for approximately nine months after the surgery.

Between 2001 and 2006, plaintiff was treated for high cholesterol, high blood pressure, and weight gain. In 2003, she had gallbladder surgery and, in 2005, experienced bowel problems. At her annual physical that year, a nurse at Likness's office diagnosed a rectocele and recommended a change in diet. During this period, plaintiff also had recurring urinary tract infections (UTIs).

On June 7, 2006, plaintiff, then forty-one, saw Benson complaining of obstructed defecation. His examination revealed a rectocele, which protruded two to three centimeters beyond the opening of the vagina. He also determined that plaintiff likely had an enterocele.[5]

Benson discussed various options, including continued observation, a pessary implant, a native tissue repair to suture

[5] One witness described an enterocele as "part of the small intestine that takes over the space where the uterus used to be."

the organs and pull them into the pelvis, and Prolift. He discussed the risk of recurrence from a traditional repair and the fact that a pessary treated symptoms but provided no cure for the rectocele. Benson discussed Prolift's risks, including exposure or erosion of the mesh into other structures, as well as bleeding, infection, and inflammation. In addition, Benson reviewed for plaintiff the risks of any vaginal surgery, including dyspareunia, scarring, and the potential for future surgery. Because he had no available copies of the patient brochure, Benson referred plaintiff to Ethicon's website. Ultimately, Benson and plaintiff concurred that a mesh implant was the best option and its benefits outweighed its risks, and plaintiff consented to the procedure.

Benson said he relied on the IFU to communicate all the risks and potential adverse effects of Prolift. He trusted Ethicon to provide fair, balanced, and truthful information in the IFU, training materials, and surgical technique guide. By the time of plaintiff's surgery, he had received training on the use of the Prolift system, trained other physicians in the surgical technique, and performed approximately fifty Prolift implants. He also then understood that if a problem arose, "removal of the mesh would improve the circumstances."

Plaintiff had the Prolift operation on July 13, 2006. The surgery involved the placement of an anterior vaginal mesh under

the bladder, resuspension of the vaginal apex, and placement of a posterior vaginal mesh. During surgery, Benson confirmed the presence of a rectocele and enterocele, and he also diagnosed a high cystocele — "a small prolapse of the bladder coming usually down in the anterior wall of the vagina."

During a follow-up visit on July 17, 2006, Benson observed the vagina was healing well, there were no signs of infection, and the defecatory dysfunction was markedly better.

On August 28, 2006, plaintiff saw Benson with complaints of pelvic pain. He found no signs of mesh erosion or extrusion and noted she was voiding better and having no problems with defecation.

On September 11, 2006, plaintiff saw Benson with complaints of persistent pelvic pain. During his physical examination, she reported pain where the superficial arm of the Prolift mesh would have penetrated through the obturator membrane. Benson infiltrated the area with a local anesthetic and a steroid.

Plaintiff obtained temporary relief, but returned on September 19, 2006, reporting the pain was worse after increasing activity and at the end of the day. Benson told her that "being patient and moving forwards to a solution [wa]s better than rushing in to perhaps hav[ing] more problems."

On September 21, 2006, Benson performed exploratory surgery.

He found nothing abnormal in the area of the anterior superficial wing but discovered some irritation inside the bladder, which was consistent with interstitial cystitis; he performed a cystoscopy. His postoperative diagnosis included left-sided perineal pain after Prolift, recurrent UTIs, and hemorrhagic cystitis.

Benson saw plaintiff four days later and reported no evidence of entrapped mesh. He further reported that the surgical site was healing well and there were no signs of infection.

On September 28, 2006, plaintiff complained of pelvic pain to Likness, but, on October 2, 2006, she reported to Benson that she was doing much better. During a follow-up visit on October 31, 2006, Benson found no evidence of erosion but felt an area of potential thickening. Benson told plaintiff he could excise a portion of the mesh but removal might produce mixed results. He explained that the mesh might not be the only etiology of her pain and expressed concern that her prolapse might return if he removed too much. Plaintiff expressed her understanding but wanted to proceed with surgery.

In his operative report dated November 9, 2006, Benson documented chronic pelvic pain and dyspareunia after vaginal mesh repair. The surgery identified a small extrusion of mesh at the posterior vaginal apex (the top of the vagina); some bunched mesh in the area where plaintiff felt discomfort was removed. Benson

explained during his deposition that the mesh was not flat — that it had "contracted into a wrinkled type of bulge" or "essentially shrunk over time." He further explained that the location of the mesh contraction was where plaintiff had complained of pain, but he did not remove the mesh wings. At a post-operative visit on November 14, 2006, Benson found no evidence of erosion.

The next day, plaintiff saw Jacalynn Lake, a physical therapist, for "left lower quadrant pain and rectus abdominous strain." As part of manual therapy, Lake placed her fingers inside plaintiff's vagina to decrease muscle tension and tightness. She described plaintiff — her former co-worker — as a different person after Prolift surgery. She observed that plaintiff had gained weight and had difficulty performing activities.

On November 29, 2006, at Benson's suggestion, plaintiff saw Michael E. Fiegen, M.D., a urogynecologist, for a second opinion about her post-operative pelvic pain. Plaintiff reported she took Toradol, an anti-inflammatory medication, to control pain and remain functional. Fiegen performed a digital palpation by pressing his fingers over the anterior compartment of the vagina, noting tissue was still healing from recent surgery. He saw no evidence of mesh erosion. He performed a cystoscopy but found no evidence of a hemorrhage to suggest persistent issues of interstitial cystitis. Fiegen's clinical impression was

"[m]yofascial pain with persistent inflammation resulting from Prolene mesh placement." Fiegen explained at trial that myofascial pain referred to muscle and fascial tissue that was part of the support systems for the pelvis, that he partly based his impression of persistent inflammation on plaintiff's positive response to anti-inflammatory medicines, and that he could not confirm his diagnosis without surgery. Fiegen recommended a complete removal of the mesh.

When plaintiff subsequently spoke with Benson about Fiegen's recommendation, Benson advised that removal of the mesh might lead to a recurrence of her prolapse and might not improve her pain. Plaintiff decided to proceed with the surgery.

On December 14, 2006, Benson removed the anterior portion of mesh in the vaginal area. Plaintiff reported relief and returned to work. Likness, who discussed plaintiff's surgery with Benson, testified they agreed she was having an immunologic response from the mesh that caused irritation, inflammation, and swelling.

By late January 2007, plaintiff's symptoms returned. She saw Benson, who found no evidence of mesh exposure or extrusion. At that time, plaintiff learned Benson had not removed the mesh arms, which Benson did not recommend due to the high risk of morbidity and of becoming incontinent. In his records, Benson reported that he told plaintiff he felt like "a dog chasing its tail in trying

to determine where this pain is at any given time." Noting her improvement after the second surgery, Benson did not believe the problem was "graft material related" and recommended conservative management.

On February 15, 2007, plaintiff saw James Raders, M.D., an urogynecologist in Minneapolis, who was also a consultant for Ethicon on such products as Prolift. Plaintiff described left-sided pain "inside her vagina" as "shooting" and "burning," explaining it was exacerbated by significant activity and by sitting for prolonged periods. Plaintiff reported abandoning vaginal sexual activity due to dyspareunia. During the physical examination, Raders found a mass or area of firmness measuring approximately five by fifteen millimeters.

Raders discussed with plaintiff the general risks of surgery such as "anesthesia, bleeding, infection, organ damage, blood clots, pneumonia, [and] death," as well as the risk of developing a fistula and advised against the removal of small amounts of mesh, explaining it could be "a hazardous dissection [and] further disturb her pelvic floor musculature and innervation and would probably not relieve, only exacerbate her existing pain syndrome." He recommended other treatment such as continued use of anti-inflammatories and physical therapy with "deep intravaginal myofascial release," i.e., deep vaginal massage of muscles.

On May 4, 2007, plaintiff saw Fiegen for persistent pain. During examination he sensed a "[s]mall residual remnant of Prolene mesh," and he injected Marcaine, a Novacaine-like drug, and a steroid over the area of the mesh to break the pain cycle. He told plaintiff that surgical intervention was then inappropriate and she should wait to see if the injections relieved her pain. He did not see her again.

On May 10, 2007, plaintiff returned to Raders, who felt the small mass described by Fiegen. Despite Raders's warning that further surgery could result in recurrent or more significant fibrosis, and that it might also exacerbate her pain, plaintiff chose to proceed. On May 22, 2007, Raders performed the surgery, finding the mass consisted of a residual piece of mesh embedded in scar tissue, and removed it. Raders testified, with some resistance, that he felt there was enough potential benefit to go forward with surgery, saying "the risks were not that great regardless of what benefit she may or may not glean from it." He testified that plaintiff's pain symptoms improved but were short-lived.

Plaintiff saw Raders again in July 2007, complaining of pain in her left gluteal area. During the exam he found mesh exposure. Raders cautioned against removal of the mesh arms, explaining it was not likely to result in global resolution of her pain because

"the previous mesh excisions had not done so." He informed plaintiff about the risks of surgery; she wanted the mesh removed. At trial, Raders said that, while not common, plaintiff's chronic pelvic pain syndrome was a complication of pelvic reconstructive surgery. On July 27, 2007, plaintiff returned to Raders, who had a "long discussion" with her about the inadvisability of any "surgical misadventure" looking for mesh arms. He again explained that, even if found, removal was "unlikely to result in global resolution of her pain."

In early October 2007, a Dr. Trabuco[6] at the Mayo Clinic performed exploratory surgery on plaintiff and found mesh wrapped around and embedded in the left ureter and additional mesh embedded in the left vaginal wall. Two weeks later, he removed the exposed mesh. Afterwards, he told plaintiff that removal of additional mesh might not alleviate the pain but might instead make it worse. Plaintiff, however, returned to Trabuco on January 24, 2008, at which time he removed more mesh.

Likness testified that two years after the Prolift surgery he continued to treat plaintiff for secondary anxiety and depression as a result of severe pain; he also testified she had no prior history of emotional issues. Likness prescribed

[6] His first name is not revealed in the record.

medication to help plaintiff sleep better and referred her to a clinical psychologist. Likness reported in his medical notes from May 2008 that plaintiff still had residual urine and required self-catherizing once or twice a day.

In June 2008, plaintiff and her husband were trying to have sexual relations when he felt a sharp object. She returned to the Mayo Clinic and, on June 24, 2008, Trabuco removed another piece of mesh.

Plaintiff subsequently saw Dr. Michael Hibner in Arizona. On June 8, 2009, he performed surgery to reduce the pain in her pudendal nerve. Afterwards, she suffered complications that required placement of a pain pump and a drainage tube. Plaintiff continued to have drainage issues and, in October 2009, underwent a procedure to remove excess scar tissue, which was preventing the wound from healing.

In January 2010, plaintiff lost her job at Prairie Lakes Hospital. In 2011, she had a job performing administrative work for two hours a day at an assisted living facility while another employee went on leave, but would arrive home in pain and exhausted. On July 24, 2012, and October 17, 2012, plaintiff went to the Mayo Clinic for Botox injections in her pelvic floor to break her spasms and relax her bladder; this provided no relief.

Likness testified that plaintiff had twenty-two surgical

procedures after her implant in July 2006, nine of which found mesh. He believed these surgeries were appropriate and necessary. In his view, the mesh had migrated. Likness explained that he, Trabuco, Hibner, and Raders had found "palpable areas of swelling, pointing, pressure, fullness that truly suggested recurrent mesh in these locations." He blamed the mesh implant for plaintiff's chronic pelvic pain, dyspareunia, bladder infections, urinary retention, pudendal neuralgia, depression, and anxiety. Likness explained that, with the exception of UTIs, plaintiff did not suffer from any of these health issues prior to the Prolift surgery, and he concluded plaintiff's problems were permanent.

Ronnie Lee Seltzer, M.D., a psychiatrist who interviewed plaintiff and reviewed her medical records in advance of trial, testified plaintiff suffered from permanent depressive and anxiety disorders caused by chronic pain syndrome.

At trial, Benson testified that plaintiff experienced a "catastrophic outcome." Although he had performed Prolift surgeries before and after July 2006, he described plaintiff's outcome as "the only one that has been that severe." Fiegen, who had performed two or three anterior Prolifts, similarly testified that plaintiff had an "unusual occurrence" and he had "not seen or heard of other physicians at conferences, at meetings, talk about a patient that had this kind of reaction."

Benson said Ethicon did not warn about the catastrophic outcome suffered by plaintiff and, if he had known about such potential complications in July 2006, he would have presented more information to plaintiff about potential risks. Benson elaborated that their discussion would have been "more robust," meaning they would have discussed all possible adverse outcomes. While he probably spent fifteen to twenty minutes with plaintiff discussing the Prolift surgery, he now spends forty-five minutes to an hour with a patient discussing whether to have the mesh implant, and reviewing the complications of mesh removal and the possibility of permanent pain.

Benson testified he would not have recommended Prolift to plaintiff if he had known about all the potential risks. For example, if he had known that patients with chronic pain had a higher chance of complications, he would have discussed this risk with plaintiff given her prior spinal headaches. Also, given that at the time of surgery plaintiff was forty-one and sexually active with no prior history of any prolapse, Benson said "with the environment that we're in today, it would essentially allow for the option of observation, of pessary or a traditional suture colporrhaphy." Even so, Benson said he still would have offered Prolift as an option for plaintiff in July 2006, explaining it is the patient who makes the final decision.

III

In appealing, defendants argue that the trial judge: (a) erred in determining that the learned intermediary doctrine did not apply to plaintiffs' deceit claim and was misapplied on plaintiffs' failure-to-warn claims; (b) mistakenly concluded that plaintiffs' causation evidence was sufficient to support a failure-to-warn claim; (c) abused her discretion in making certain evidence rulings; and (d) erroneously permitted the punitive damage award to stand.[7] We reject these arguments and affirm.

A

In their arguments about the learned intermediary doctrine, defendants contend that the trial judge (1) erred in failing to conclude the doctrine barred plaintiffs' deceit claim as a matter of law, and (2) misapplied the doctrine to plaintiffs' failure-to-warn claim. Before considering those precise contentions, we first make the following observations about the doctrine.

[7] Because we do not reverse with regard to any of these issues, defendant's fifth point – in which they argue "because the jury returned a general verdict on punitive damages, a new trial is required if the court reverses one or the other of plaintiffs' underlying claims" – is moot.

The learned intermediary doctrine[8] imposes a duty on a manufacturer to warn physicians of the risks involved with its product, thereby placing the physician in the role of intermediary between manufacturer and patient. See Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004) (North Dakota law); McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 231 (D.S.D.), aff'd, 739 F.2d 340 (8th Cir. 1984).[9] Thus, the law considers a manufacturer's warning to a physician to be a warning to the patient, and a manufacturer "need not communicate directly with all ultimate users" of its product. In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002), aff'd sub nom. White v. Wyeth Labs., 69 F. App'x 658 (5th Cir. 2003).

The doctrine, however, does not allow or presuppose that physicians "substitute their judgment for that of their patients." Gilliland v. Novartis Pharm. Corp., 34 F. Supp. 3d 960, 972 (S.D. Iowa 2014). And the learned intermediary doctrine does not

[8] The parties agree South Dakota law applies but that its highest court has not spoken on the subject. In Schilf v. Eli Lilly & Co., 687 F.3d 947, 949 (8th Cir. 2012), the court determined that the South Dakota Supreme Court would likely adopt the learned intermediary doctrine as well as the heeding presumption that "a reasonable person . . . would act according to an adequate warning."

[9] The court of appeals in McElhaney held only that the district court's interpretation of South Dakota law was reasonable. 739 F.2d at 340.

eliminate a factfinder's need to consider whether the patient's decision would have been different if the warning had been sufficiently thorough. Ibid. Instead, the doctrine's purpose is "to enable patients to make informed and intelligent decisions whether to undergo a recommended therapy by balancing the probable risks against the probable benefits of the course of treatment proposed by their physicians." Ibid.

(1)

In considering plaintiffs' deceit claim, and the impact — if any — of the learned intermediary doctrine, we first observe that the deceit cause of action in South Dakota is a statutory creature. South Dakota's Legislature has determined that "[o]ne who willfully deceives another, with intent to induce him to alter his position to his injury or risk, is liable for any damage which he thereby suffers." S.D. Codified Laws § 20-10-1. Deceit is either:

> (1) The suggestion, as a fact, of that which is not true, by one who does not believe it to be true;
>
> (2) The assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true;
>
> (3) The suppression of a fact by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact; or
>
> (4) A promise made without any intention of performing.

[S.D.C.L. § 20-10-2.]

A deceit claim, therefore, requires "proof of an intentional misrepresentation or concealment of a fact on which plaintiff relied and that caused an injury to plaintiff." Northwestern Pub. Serv. v. Union Carbide Corp., 236 F. Supp. 2d 966, 973-74 (D.S.D. 2002); see also Arnoldy v. Mahoney, 791 N.W.2d 645, 660 (S.D. 2010).

Plaintiffs' proofs were clearly sufficient to meet this standard. Owens testified she knew about the risks of dyspareunia and severe pain, but did not include them in Ethicon's warnings because she expected surgeons to discuss them with their patients. Hinoul similarly stated that the IFU, and by extension the patient brochure, did not identify all potential risks. Likewise, Arnaud acknowledged he was aware of problems with Prolift before it went on the market; he was aware of the potential risks of mesh erosion, pain, and dyspareunia, as well as the need to improve the mesh material, but believed it was the surgeon's duty to develop solutions. These known circumstances were not fully identified in the warnings rendered by the time of plaintiff's surgery because, as we noted earlier, the IFU and other materials had already gone to the printer and defendants were desirous of placing the product in the marketplace as soon as possible.

Also, plaintiff testified she visited defendants' website to review the patient brochure, that she relied on the information in the brochure in making her decision to use Prolift, and that she would have decided against the mesh implant if all risks had been disclosed. The record, therefore, contains sufficient evidence from which the jury could have found defendants willfully deceived plaintiff by providing intentionally misleading information in the patient brochure and by suppressing facts they were bound to disclose, that they made the misrepresentations to induce plaintiff to use the Prolift system, that plaintiff relied on the information in the brochure, and that she suffered damages as a result of their deception.

We agree with plaintiffs that the learned intermediary doctrine cannot serve to negate the deceit claim. It may be that in enacting the cause of action of deceit without incorporating the learned intermediary doctrine, South Dakota's Legislature intended to exclude its application; this argument has a common-sense appeal. But, here, the jury determined that defendants failed to give adequate notice to plaintiff's physician; consequently, even if South Dakota recognized the learned

intermediary doctrine,[10] it would not likely be applied once there is a determination of an inadequate warning. That is, as our courts have recognized, when there is a failure to adequately warn the physician, the learned intermediary doctrine as a defense simply drops away. See Perez v. Wyeth Labs. Inc., 161 N.J. 1, 19 (1999) (recognizing the learned intermediary doctrine is "an exception to the manufacturer's traditional duty to warn consumers directly" so that, when "its premises are absent," the defense "simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with general principles of tort law"). In other words, in that circumstance, the intermediary cannot be said to be adequately learned because he or she was not adequately informed.

For these reasons, we find no merit in defendants' argument that the doctrine should have barred the deceit claim.

(2)

Defendants also contend the trial judge misapplied the learned intermediary doctrine to plaintiffs' failure-to-warn claim by giving a causation instruction that allowed the jury to bypass

[10] It is not entirely clear that this will occur, although most states have adopted the doctrine. South Dakota's pattern jury instructions, which have been "carefully drafted to reflect the law," State v. Eagle Star, 558 N.W.2d 70, 73 n.2 (S.D. 1996), do not include the learned intermediary doctrine as a defense to such an action.

the doctrine. They argue this instruction allowed the jury to find causation based on plaintiff's review of the patient brochure without regard to the warnings provided to Benson as the learned intermediary. We disagree.

At the charge conference, the judge found the patient brochure was "not part of the failure to warn strict liability [claim], which has a learned intermediary doctrine," but instead was "part of proximate cause." The judge also found that "proximate cause has to include [plaintiff's] decision-making process," and explained the proximate cause charge had to make clear to the jury that the decision involved both the physician and the patient and that, even if Benson had been willing to use the Prolift system, plaintiff might have declined if she had known of all the risks.

In the charge as delivered to the jury, the judge instructed that plaintiffs were required to prove defendants gave Benson inadequate warnings about the Prolift system and that, in evaluating the warnings, it could consider the IFU, patient brochure, and surgical guide. The judge further instructed the jury that plaintiffs were required to prove the alleged failure to warn was a proximate cause of Linda's injury. After charging the jury on the meaning of proximate cause, the judge added:

> If you find that defendants did not provide an adequate warning, plaintiff also must prove that an adequate warning would have caused Dr.

> Benson not to prescribe and use the Prolift system or Linda Gross not to agree to the use of the Prolift system.
>
> [Emphasis added.]

No objection was lodged before the jury began deliberations.

Jury instructions, of course, should correctly state the law in clear and understandable language. Mogull v. CB Commercial Real Estate Grp., Inc., 162 N.J. 449, 464 (2000); Boryszewski v. Burke, 380 N.J. Super. 361, 374 (App. Div. 2005), certif. denied, 186 N.J. 242 (2006). When reviewing jury instructions, we are required to read the charge as a whole and will not intervene if the charge "adequately conveys the law and does not confuse or mislead the jury." Sons of Thunder, Inc. v. Borden, Inc., 148 N.J. 396, 418 (1997). Our standard of review prevents us from intervening unless the jury could have reached a different result had the court provided the correct instruction. Viscik v. Fowler Equip. Co., 173 N.J. 1, 18 (2002). Absent an objection, an appellant must convince us that the error was clearly capable of producing an unjust result. R. 2:10-2.

Causation is "an essential element in a failure[-]to[-]warn claim," Burley v. Kytec Innovative Sports Equip., Inc., 737 N.W.2d 397, 410 (S.D. 2007), and "ultimately rests with the patient's decision to take or reject" the product offered, Payne v. Novartis Pharm. Corp., 767 F.3d 526, 532 (6th Cir. 2014) (applying Tennessee

law). See also In re Prempro Prods. Liab. Litig., 586 F.3d 547, 570 (8th Cir. 2009) (finding, pursuant to Arkansas law, sufficient evidence for a jury to determine a failure to warn was the proximate cause of the plaintiff's injuries and that the patient would not have chosen hormone replacement therapy if she had known of the risk of breast cancer); Restatement (Third) of Torts: Products Liability § 6 cmt b (1998) (explaining that a health care provider has a duty "to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy"). The South Dakota Supreme Court has emphasized a similar "patient-oriented" standard in informed consent cases. Savold v. Johnson, 443 N.W.2d 656, 659 (S.D. 1989) (holding that the rule to determine whether adequate information was provided to a patient was whether a reasonable person would not have agreed to the proposed treatment if told beforehand of the risk which resulted in injury); Wheeldon v. Madison, 374 N.W.2d 367, 374 (S.D. 1985) (holding "the right to know — to be informed — is a fundamental right personal to the patient and should not be subject to restriction by medical practices that may be at odds with the patient's informational needs").

The judge instructed the jury that plaintiffs were required to prove an adequate warning would have caused Benson to recommend

against the Prolift system or plaintiff to decline its use. As explained elsewhere in this opinion, the record is replete with evidence from which the jury could conclude that adequate warnings would have caused Benson to alter his recommendation to use the Prolift system and plaintiff to choose another treatment option. Among other things, Benson said that he relied on the IFU as a complete statement of the risks, that, in light of defendants' warnings, he believed the benefits of Prolift outweighed the risks, and that he decided the mesh implant was the best option. Benson testified he recommended Prolift, but plaintiff made the final decision to proceed with the surgery. Benson and plaintiff, however, testified they would not have proceeded with Prolift if all risks known at the time of her surgery — such as chronic pain, the difficulty of mesh removal, and the possibility of multiple post-implantation surgeries — were disclosed.

The jury was presented with sufficient evidence by which it could reasonably conclude that the lack of adequate warnings was a proximate cause of plaintiff's injuries.

B

Defendants argue the judge erred in denying their motion for judgment as a matter of law on the failure-to-warn claim, asserting the causation evidence was insufficient to support the jury's verdict. We reject this contention.

The judge determined there was "extremely strong" evidence to support plaintiffs' position that defendants failed to provide adequate warnings to Benson. She found the documents and testimony of experts and witnesses, including defendants' employees, showed that Prolift could cause severe injuries and that its removal could lead to catastrophic complications:

> [P]laintiffs presented a lot of evidence that certainly could support a finding by the jury that this was a very risky product, that particularly when it came to the removal of the product, where it didn't work properly, that a woman was — could be faced with very, very substantial risks to her well-being and to her quality of life and substantial pain, loss of sexual activity, all kinds of different problems in addition to numerous surgeries. And the testimony could have been believed, . . . and apparently was believed by the jury, . . . that the defendant knew about this problem, that they were told about this problem, that their own doctors were warning them about this problem, that their own studies were showing this problem, that this was a major, major problem and not an uncommon problem, and therefore, that the defendant had a duty to warn about the problem.

The judge also observed it was "obvious" from Benson's testimony

> that the risks with this product, which were known to the defendants, . . . were not known to the doctor, were not conveyed to the doctor and that in fact if [they] had been conveyed, the doctor would have made a different decision.

In support, the judge cited Benson's testimony that if he had known Prolift should not be implanted in sexually active people, he would not have chosen this treatment for plaintiff and, at the very least, he would have spent forty-five minutes to an hour discussing the risks with her. The judge also relied on plaintiff's testimony that she would not have selected the Prolift option if she had known of the risks and recognized there was overwhelming evidence to show the company had information about Prolift that it chose not to provide to the physician.

To prevail on a claim for strict liability failure to warn, under South Dakota law, a plaintiff must show:

> 1. a danger existed associated with a foreseeable use of the product;
>
> 2. an inadequate warning was given regarding the danger;
>
> 3. as a result of the inadequate warning, the product was rendered defective and unreasonably dangerous;
>
> 4. the defective and unreasonably dangerous condition existed at the time it left the control of the manufacturer;
>
> 5. the product was expected and did reach the user without a substantial unforeseeable change in the condition that it was in when it left the manufacturer's control; and
>
> 6. the defective condition was the legal cause of [her] injuries.
>
> [Burley, supra, 737 N.W.2d at 409.]

"Proximate or legal cause is a cause that produces a result in a natural and probable sequence and without which the result would not have occurred." First Premier Bank v. Kolcraft Enters., Inc., 686 N.W.2d 430, 454 (S.D. 2004). A proximate cause does not have to be the only cause but may act in combination with other causes; it almost always presents a fact question, except where the evidence is such that there are no differences of opinion. Ibid.

The evidence was sufficient to allow the jury to find an adequate warning would have prevented plaintiff's injuries. Benson testified he read and relied on the warnings in the IFU, assumed the IFU provided a comprehensive list of the risks and potential complications, and trusted Ethicon to provide "truthful and complete" information.

After plaintiff's surgery, Benson learned "a great deal more" about the risks of the Prolift system. For example, at the time of the implant surgery in July 2006, he understood that the risk of erosion was low and that its removal, if an issue arose, would improve a patient's circumstances. He later learned about the complications surrounding mesh removal, the possibility of multiple post-implantation surgeries, and the chance that removal of the mesh might not resolve the patient's problems. Also after plaintiff's surgery, he learned about the risks of chronic pelvic

pain and inflammation, and the consequences of mesh contraction.

Benson acknowledged that if he had known about the additional risks in July 2006, he would have offered — but not recommended — Prolift to plaintiff as an option. Given her age at the time of surgery (forty-one) and active lifestyle, and the fact this was her first prolapse surgery, he would have allowed for the options of observation, a pessary, or a traditional suture colporrhaphy. He also said their discussion about the Prolift system would have been more robust, that it would have included every possible adverse outcome, and that it would have lasted forty-five minutes to an hour, instead of the fifteen to twenty minutes he spent with plaintiff. When asked to list all the risks that he discussed with his patients after July 2006, Benson answered:

> [I]t would define about everything that could be possibly thought of that could happen related to a surgery: Infection, bleeding, injuring the bladder, the bowel, the ureters, the urethra, dyspareunia, vaginal discharge, pelvic pain, centralized pain, vaginal foreshortening, constricture, impaired recovery. These are just some of the topics that we talk about.

Plaintiff confirmed she would not have agreed to use Prolift had she known all the risks. For example, she did not know about the risks of mesh contraction, chronic pelvic pain, dyspareunia, or permanent urinary retention. She also did not know about the difficulties surrounding mesh removal. She explained that the

patient brochure reassured her that complications were rare and the risk of mesh erosion was small.

There was also ample evidence that defendants were aware of additional risks at the time of Prolift's launch. Ciarrocca testified he knew about the results of the French TVM study, which warned against the use of Prolift in sexually active women and in those who had hysterectomies, but these warnings were not included in the IFU because Ethicon had already printed launch stock and the company wanted to get the product to market as soon as possible. Similarly, Owens testified that at the time of Prolift's launch she knew mesh could erode or migrate or lead to inflammation, that the removal of mesh could be very difficult, and that the November 2004 article by the French TVM group had identified the risks of severe pain and dyspareunia. She also knew the mesh implant might cause long-term complications.

Defendants argue that Benson's testimony relied on circumstances that post-dated plaintiff's surgery. Although he admittedly lacked knowledge in July 2006 about certain risks, the appropriate question is whether Benson would have prescribed the Prolift implant if Ethicon had provided adequate warnings of the risks it was aware of at that time. There was sufficient evidence for the jury to find that if Ethicon had placed adequate warnings in the IFU, the warnings would have altered Benson's conduct and

prevented plaintiff's injuries.[11]

C

Defendants urge that we find an abuse of discretion in the admission of evidence about: (1) subsequent changes to Prolift's IFU regarding warnings; (2) the so-called "destroyed vagina" email; and (3) the cross-examination of a defense expert about her failure to respond to inquiries for information about a former patient. In considering these arguments, we rely on our standard of review, which recognizes that trial judges possess broad discretion in performing their gatekeeping role in the admission or exclusion of evidence. Verdicchio v. Ricca, 179 N.J. 1, 34 (2004). We will not intervene unless the ruling "was so wide of the mark that a manifest denial of justice resulted." Green v. N.J. Mfrs. Ins. Co., 160 N.J. 480, 492 (1999); Bitsko v. Main Pharmacy, Inc., 289 N.J. Super. 267, 284 (App. Div. 1996).

(1)

Defendants argue the judge abused her discretion in her ruling about the FDA's clearance of Prolift and the concomitant revised warnings that occurred after plaintiff's implant surgery. We find

[11] Rodriquez v. Stryker Corp., 680 F.3d 568, 576-77 (6th Cir. 2012), and Motus v. Pfizer Inc., 196 F. Supp. 2d 984 (C.D. Cal. 2001), aff'd as mod., 358 F.3d 659, 661 (9th Cir. 2004), upon which defendants rely, do not persuade; those courts found insufficient evidence to prove causation because, unlike Benson, the physicians there never read the manufacturer's warnings.

no merit in this argument.

The record demonstrates that in pretrial proceedings, defendants were desirous of providing evidence that Prolift was cleared by the FDA in May 2008; the judge, however, correctly ruled that in fairness, and with appropriate limitations,[12] plaintiffs would be permitted to offer evidence of the revised Prolift warnings. This double-edged sword posed a tactical problem for defendants that limited the proofs regarding both FDA clearance and subsequent product warnings. Although defendants chose not to open the door, they later argued that the exclusion of FDA clearance was erroneous and prejudicial. The judge responded in her post-trial decision that defendants' position in this regard was "disingenuous" because she had ruled that the "defense had the right to bring that evidence in, and I repeatedly told them, go ahead and ask the question" but "they didn't want some of the subsequent actions in. That was their choice. It was a strategy call that they made during trial." We agree; defendants made a choice and should not now be heard to complain about the consequences of that choice. See Brett v. Great Am. Recreation,

[12] For example, plaintiffs were not permitted to argue or seek admission of evidence that: "[d]efendants' conduct was illegal or criminal; that [d]efendants committed fraud on the FDA; that the Prolift should have been designated a Class III device by the FDA; or reference in any way the Prolift's withdrawal from market."

Inc., 144 N.J. 479, 504-05 (1996).

If, however, the judge's ruling that admission of FDA clearance was conditioned upon admission of the revised warnings was erroneous, we would agree defendants should not have been placed in that strategic quandary. This turns on the question of whether the revised warnings were mandated, which would fall within an exception to N.J.R.E. 407's ban on evidence of subsequent remedial measures, Cepeda v. Cumberland Eng'g Co., 76 N.J. 152, 193-94 n.11 (1978), overruled on other grounds, Suter v. San Angelo Foundry & Mach. Co., 81 N.J. 150, 177 (1979), or voluntarily adopted, which would preclude admission, Harris v. Peridot Chem. (N.J.), Inc., 313 N.J. Super. 257, 292 (App. Div. 1998).[13] We are satisfied the information provided to the judge supported her determination that the warnings were mandated and the revised-warnings evidence admissible if evidence of FDA clearance was elicited.

The record reveals that, on June 1, 2007, defendants prepared a "Traditional 510(k) Premarket Notification" for the Prolift+M system, which used a polypropylene mesh in combination with other

[13] N.J.R.E. 407 generally precludes evidence of subsequent remedial measures not because the evidence lacks relevancy but because its admission "might discourage corrective action and induce perpetuation of the damage and condition that gave rise to the lawsuit." Hansson v. Catalytic Constr. Co., 43 N.J. Super. 23, 29 (App. Div. 1956).

material. Ethicon sought 510(k) clearance for the Prolift+M system and, on July 19, 2007, provided information to the FDA to "assist with the delineation between GYNECARE GYNEMESH, GYNECARE PROLIFT, and GYNECARE PROLIFT+M." On July 31, 2007, the FDA notified Ethicon that the changes to Gynemesh PS required "at minimum" an "Add-to-File," including: information about specific changes made to the device originally cleared; a statement of whether these changes altered the safety or effectiveness of the product as compared to the original device; and "[a]ny and all relevant tests and data related to the performance of the new, altered device (in this case the Gynecare Prolift Repair System)."

On August 6, 2007, Ethicon submitted additional information, advising the FDA that the change from Gynemesh PS to the Prolift system was considered "an insignificant change" and that "it was deemed that no Premarket Notification was necessary" for the Prolift system.

On August 24, 2007, the FDA requested further data on Prolift+M as well as Prolift, noting potential issues with the Prolift system's safety and efficacy given the complexity of the procedure and high risk for organ perforation. The FDA advised Ethicon that the amendment submitted as an add-to-file was converted to a 510(k) submission for the Prolift system and that other essential items were necessary, such as device labeling.

In its response on September 20, 2007, Ethicon advised that "[o]riginally, PROLIFT was provided as a predicate device for the surgical placement of the PROLIFT+M mesh," but the Prolift system was "now considered part of this [510(k)] submission." The same day, the FDA advised Ethicon that it did not completely respond to the deficiencies listed in the August 24 letter and that it required a detailed summary of clinical data for Prolift and a revised labeling for review. At a conference on January 22, 2008, Ethicon and the FDA met to discuss the questions raised by the agency and, on May 9, 2008, Ethicon responded to the FDA's questions with revised IFUs and patient brochures for the Prolift and Prolift+M. As represented by defendants, the FDA granted 510(k) clearance to Prolift in May 2008, "with a revised IFU that included additional warnings and omitted several statements contained in the original IFU."

Clearly, the revised warnings were a response to changes mandated by the FDA and not what defendants refer to as Ethicon's "significant initiative." In support, defendants argued they successfully resisted some revisions proposed by the FDA and introduced others on their own, suggesting the revised label was a result of "voluntary back-and-forth" discussions. This argument misses the point. The FDA informed Ethicon that it needed revised labeling for Prolift and, therefore, the revisions were not

voluntary. In any event, the matter rested in the trial judge's exercise of discretion as to which we find no abuse.

(2)

Defendants argue the trial judge abused her discretion by admitting into evidence a 2009 email from Dr. Fah Che Leong, describing a patient who suffered a "permanently destroyed vagina" as a result of Prolift surgery. They argue this evidence constituted inadmissible hearsay, was not relevant because it post-dated plaintiff's surgery by almost three years, and was highly prejudicial.

At trial, the judge overruled defendants' objection, finding that Hinoul, the designated Ethicon representative on medical affairs, identified Leong's email as an adverse event report. The judge further found that Hinoul said Ethicon monitored their products by: reaching out to customers for feedback; encouraging company dialogue with surgeons who used the Prolift system; providing the adverse event reports to the FDA; and retaining these reports as part of their records.

The business exception to the ban on hearsay provides:

> A statement contained in a writing or other record of acts, events, conditions, and, subject to Rule 808, opinions or diagnoses, made at or near the time of observation by a person with actual knowledge or from information supplied by such a person, if the writing or other record was made in the

> regular course of business and it was the regular practice of that business to make it, unless the sources of information or the method, purpose or circumstances of preparation indicate that it is not trustworthy.
>
> [N.J.R.E. 803(c)(6).]

A statement falls within this exception when it is shown that: (1) the writing was made "in the regular course of business"; (2) the writing was "prepared within a short time of the act, condition or event being described"; and (3) "the source of the information and the method and circumstances of the preparation of the writing justify allowing it into evidence." Feldman v. Lederle Labs., 132 N.J. 339, 354 (1993) (quoting State v. Matulewicz, 101 N.J. 27, 29 (1985)).

Hinoul testified that, on February 19, 2009, Leong, an urogynecologist at St. Louis University, sent an email to Scott Jones,[14] a product director for Prolift who worked in Ethicon's marketing department, stating that he was taking to the operating room a patient who had an anterior and posterior Prolift implanted by another physician. Leong informed Jones that the patient had mesh extruding "literally everywhere," that she would "likely lose any coital function" and that she had "a large stone in the bladder

[14] Leong's email was written in response to an email from Jones, asking if Leong still had an interest in using the Prolift system and if a proposed training agenda would meet his needs.

from a bladder perforation with the anterior arm." Leong wrote that he would no longer perform these procedures and that he "bet" a majority of surgeons using the mesh kit were not qualified to do so, adding: "This patient will have a permanently destroyed vagina, and I am only hoping to get her out of this without more morbidity."

According to Hinoul, at the time of Prolift's launch, Ethicon knew that in rare instances the Prolift could lead to mesh extrusion, pain with intercourse, and very serious damage to a woman's vagina. When asked how many times he learned of women who suffered mutilated or destroyed vaginas due to Prolift, Hinoul said he was aware of "a couple of case reports."

Hinoul said it was Ethicon's goal as a company to continuously improve its devices and explained that seeking information was part of an ongoing process – that the company valued feedback for use in its business and wanted to hear "all sides of the story." Ciarrocca similarly testified Ethicon relied on feedback from implanting surgeons that came through many channels, including email. Leong's email satisfied the first requirement of the hearsay exception because it was written in the regular course of Ethicon's business. The email also met the second requirement in that Leong wrote it as he was preparing to take his patient into the operating room, purportedly with actual knowledge of the patient's

complications. And the email met the third requirement because it was prepared by a physician who had used Prolift in the past and had been in prior contact with Jones at Ethicon. Both the source of the information and the circumstances of its preparation suggested the email's reliability and trustworthiness.

We agree, however, its relevance was of limited value because the email post-dated plaintiff's surgery. In addition, the email's colorful language carried a significant prejudicial sting. We do not doubt that the judge would have acted well within her discretion had she excluded the email through application of N.J.R.E. 403.

Notwithstanding whether it was erroneously admitted, we find the jury's consideration of the email was not clearly capable of generating an unjust result. Defendants had an ample opportunity to cross-examine Hinoul about the document and emphasize the fact that the email post-dated plaintiff's implant surgery. Moreover, any prejudice was not as significant as suggested by defendants because Hinoul's testimony fully demonstrated Ethicon knew about all potential complications from Prolift surgery from the beginning:

> Q. So, any adverse reaction, adverse event that's documented right up till the present, medical affairs knew it the day the Prolift was put on the market, right?

A. Yes. So the adverse event profile hasn't changed over the period that we've put it on the market.

. . . .

Q. And every single complication and all the damage from the other surgeries and everything we've discussed, medical affairs knew on day one before the Prolift ever went out on the market, this was going to happen to some patients due to the Prolift and its complications. Correct?

A. Yes. Because that's the —

Q. The answer is yes. Right?

A. It starts in 2003.

Q. The answer is yes. Right?

A. Yes.

Owens similarly testified that before the launch of Prolift in March 2005 she knew mesh could erode or migrate, and cause severe pain and dyspareunia.

Because defendants were aware of all known adverse reactions "from day one," the fact that the email in question post-dated plaintiff's surgery is of limited significance. Even if we were to agree this email was more prejudicial than probative and should, therefore, have been excluded, we find that it had a limited impact when considering the great amount of other similar evidence presented to the jury.

(3)

Defendants contend plaintiffs were unfairly permitted to attempt to undermine the credibility of defendants' expert in urology, Elizabeth Kavaler, M.D., by asking during cross-examination about her failure to respond to out-of-court inquiries about a former Prolift patient.

Kavaler, board certified and licensed in New York, testified she had performed "1500, 1800" prolapse repair surgeries, including 350 or 400 Prolift implants and acted as a consultant to pharmaceutical companies, including defendants. Kavaler reviewed plaintiff's medical records, depositions of her treating physicians, and some expert reports. She also examined plaintiff on September 24, 2012, and observed no exposed mesh or evidence of infection, inflammation or contraction. Instead, she found good healing of vaginal tissues with "a little bit of thickening" at the top of the vagina, which was probably scar tissue. She also observed an incision across plaintiff's buttocks, where muscles on one side had dropped lower than the other.

Kavaler recognized that plaintiff had vaginal surgery in 2001 (hysterectomy) and 2006 (rectocele), after which she had three surgeries in a very short time. Kavaler opined these surgeries caused the nerve supply in the pelvic floor to become "overactive," resulting in diffuse pain, and she believed the pain was consistent

with muscle spasms. She explained that muscle spasms were common after pelvic floor surgery and were the result of positioning, instrumentation, dissection or incisions and, also, that spasms tended to migrate, did not necessarily occur at the surgical site, and got worse with activity.

In Kavaler's opinion, plaintiff did not give her body a chance to heal from the muscle spasms and subsequent operations "continued to create trauma." She believed plaintiff's initial pain was a routine side effect of the Prolift implant and the chronic pelvic spasms were caused by the additional surgeries. She explained mesh did not migrate and mesh pieces removed by Raders and Trabuco were located in areas where vaginal tissue had become thin due to multiple incisions and closures. Kavaler also did not believe Prolift was the source of plaintiff's urinary retention and noted that plaintiff did not develop this problem until eighteen months after the initial prolapse surgery. Although acknowledging plaintiff suffered from urinary retention, chronic pelvic pain, pudendal neuralgia, and dyspareunia, Kavaler believed these problems started with the post-Prolift surgeries and that "[t]aking out the mesh did not help." Thus, in Kavaler's opinion, Prolift was an effective treatment for plaintiff's pelvic organ prolapse.

Turning to the particular issue at hand, during cross-

examination, plaintiffs' counsel asked Kavaler about a telephone call he made to her office in December 2010 to talk about one of her patients. Defense counsel objected and, at side bar, plaintiffs' counsel argued he tried to contact Kavaler three times, that she would not return his calls, and that these actions showed bias against plaintiffs. The judge overruled the objection, finding a jury could consider the witness possessed a general antagonism towards plaintiffs' lawyer as a basis of bias and as relevant to her credibility. Consequently, plaintiffs' counsel asked Kavaler, in the presence of the jury, if she recalled being contacted in December 2010 by an attorney regarding one of her patients with a Prolift implant who had filed a lawsuit. Kavaler replied: "That's correct. I did. It was from you." She also acknowledged receiving a call and two letters, and not answering them. Kavaler explained she could not speak to the attorney without HIPAA[15] authorization and that the patient would not speak with her.

To be sure, "[e]xtensive cross-examination of experts is generally permitted," but "subject to reasonable limitations imposed by the trial court in its discretion." Nowacki v. Cmty. Med. Ctr., 279 N.J. Super. 276, 290 (App. Div.), certif. denied,

[15] Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C.A. §§ 1320d-1 to -9.

141 N.J. 95 (1995). A judge's rulings that impact the scope of cross-examination will not be disturbed absent a showing of clear error and prejudice. Prioleau v. Kentucky Fried Chicken, Inc., 434 N.J. Super. 558, 587 (App. Div. 2014), aff'd in part and modified in part, 223 N.J. 245 (2015).

We agree with defendants that permitting this excursion – for the sole purpose of suggesting that Kavaler was biased against plaintiffs – into plaintiffs' counsel's failed communications with Kavaler about another patient constituted a mistaken exercise of the judge's discretion. We do not, however, find that it constitutes a valid ground for granting a new trial. It was only a brief side trip during the course of this lengthy trial, and the circumstances were not repeated during plaintiffs' closing statement to the jury.

Moreover, as Kavaler explained, it would have been improper for her to speak to an attorney about another patient without that patient's consent, thereby posing a legitimate question about the bona fides of the attorney in attempting to communicate with her in the first place. Indeed, even if the doctor had been given consent by her former patient, she was under no obligation to take counsel's telephone call. To suggest otherwise – as plaintiffs were permitted to do through this brief examination of Kavaler –

constitutes a complete misreading of our case law on the subject.[16] Kavaler owed counsel no courtesy and was not obligated to speak to him when he telephoned, and the argument that her failure to take the phone call demonstrated bias is utterly without merit. The testimony should not have been permitted, but that error does not require a new trial.

D

Defendants argue that the judge erroneously denied their motion to vacate the punitive damages award because, in their view, it was not supported by the evidence and not permitted by the New Jersey Products Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11. The judge found the PLA did not bar an award of punitive damages because the PLA only bars punitive damages for devices with premarket approval. The judge also found the award was reasonable in its amount and justified under the circumstances; to the judge, the award was not excessive, shocking, or unjust, and fell within the parameters suggested by N.J.S.A. 2A:15-5.12.

[16] In support of the argument that this cross-examination was permissible, plaintiffs refer us to In re Pelvic Mesh/Gynecare Litigation, 426 N.J. Super. 167, 186 (App. Div. 2012), where, to the contrary, we "disavow[ed] any suggestion that a physician, or any witness for that matter, has a duty to support substantively a litigant's claims or defenses. The duty of a witness is to tell the truth when testifying and to provide information accurately in anticipation of testimony. No physician or other witness has a duty to support the 'litigation interests' of a party to a lawsuit in the sense of supporting the party's claims or defenses."

Punitive damages are awarded to deter egregious conduct and punish the offender. Longo v. Pleasure Prods., Inc., 215 N.J. 48, 57 (2013). The Punitive Damages Act, N.J.S.A. 2A:15-5.9 to -5.17, allows such damages only if:

> the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof may not be satisfied by proof of any degree of negligence including gross negligence.
>
> [N.J.S.A. 2A:15-5.12(a).]

"'Wanton and willful disregard' means a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." N.J.S.A. 2A:15-5.10. In determining whether to award punitive damages, a trier of fact must consider all relevant evidence, including, but not limited to:

> (1) The likelihood, at the relevant time, that serious harm would arise from the defendant's conduct;
>
> (2) The defendant's awareness of reckless disregard of the likelihood that the serious harm at issue would arise from the defendant's conduct;
>
> (3) The conduct of the defendant upon learning that its initial conduct would likely cause harm; and

> (4) The duration of the conduct or any concealment of it by the defendant.
>
> [N.J.S.A. 2A:15-5.12(b).]

It, therefore, is essential that all relevant circumstances, including the nature of the defendant's misconduct and the harm to the plaintiff, be considered. See Herman v. Sunshine Chem. Specialties, Inc., 133 N.J. 329, 338 (1993).

Punitive damages are available in failure-to-warn, strict products liability actions. Ibid. Such damages are appropriate where the manufacturer knew of the dangers created by its product and failed to warn users of serious health hazards. Fischer v. Johns-Manville Corp., 103 N.J. 643, 670-71 (1986). In fact, punitive damages "serve as the only deterrent to manufacturers who would purposefully market dangerous products with insufficient warnings." Ripa v. Owens-Corning Fiberglas Corp., 282 N.J. Super. 373, 396 (App. Div.), certif. denied, 142 N.J. 518 (1995).

The evidence more than adequately supported the jury's award of punitive damages. In March 2005, defendants knew of additional risks omitted from the IFU and patient brochure. Owens, Arnaud and Hinoul acknowledged that potential complications such as mesh retraction, dyspareunia, and severe pain, as well as the difficulty of mesh removal, were known at the time of Prolift's launch, but were not mentioned by name in either document. And Ciarrocca

testified Ethicon did not incorporate into the IFU the warning proposed by Arnaud in January 2005 regarding mesh retraction and pain during sexual intercourse because the document was already at the printers and the company wanted to get the product to market as soon as possible.

Experts confirmed the IFU did not include all known complications. For example, plaintiffs' urogynecology expert, Anne Weber, M.D., testified that, before Prolift's launch, Ethicon knew Gynemesh PS would cause "an inordinate number of complications" based on emails from the French TVM group reporting too much mesh contraction and erosion, and she identified twenty-eight warnings that defendants did not include in the IFU. Even a defense expert acknowledged the IFU should have listed such risks as erosion, contraction, and punctures of organs, because these were complications a reasonable surgeon would not automatically think would occur with Prolift.

Surgeons also advised Ethicon about complications arising from the mesh implant, including a patient's inability to void after surgery and dyspareunia with pain at the six-arm insertion point. For example, in November 2005, Eberhard notified Arnaud that insertion of the Prolift straps or arms required too many steps, that the guide was too sharp and presented a risk of vessel or bowel perforation, and that during the cannula's removal, the

straps assumed a rope-like shape, which caused some patients discomfort.

There also was evidence of clinical studies and reports which raised warnings about the Prolift system. A March 2005 article by the French TVM group raised concerns about the level of mesh exposure in patients eight weeks after surgery and recommended caution when carrying out the new procedure. In May 2005, Arnaud and Kammerer wrote a report in which they concluded that Ultrapro mesh was a reasonable substitute for the Gynemesh PS material used in Prolift. In June 2006, shortly before plaintiff's implant surgery, the French TVM group published the results of another study showing that the prolapse recurrence rate twelve months after Prolift surgery did not meet the pre-defined criteria for success of less than twenty percent. By avoiding premarket approval, Ethicon did not conduct clinical studies or test the use of its specially designed instruments to implant the Prolift mesh in a "live person" before its launch.

The jury was entitled to find from this and other evidence that defendants provided warnings so deliberately misleading as to warrant the imposition of punitive damages. When considering the nature of defendants' misconduct and the serious harm to plaintiff, the award of punitive damages was justified. See Ripa, supra, 282 N.J. Super. at 380-82 (holding sufficient evidence in

failure-to-warn case for punitive damages, where manufacturer ignored internal testing and external reports revealing serious health risks and failed to conduct follow-up tests).

Defendants also contend there was insufficient evidence of wanton and willful disregard on the deceit claim. They argue inclusion in the patient brochure of "reasonably debatable statements" did not constitute conduct that recklessly exposed plaintiff to a high risk of harm. But the evidence – let alone common sense – suggested patients would rely on the brochure and assume Ethicon would tell them the truth about the benefits and risks of Prolift, and that the brochure, which referred to Prolift as a minimally invasive surgical technique that offered long-term results, played a role in the physician-patient discussion. The brochure's omissions and misrepresentations were relevant to the jury's consideration and support of its award of punitive damages.

Lastly, we observe that defendants do not argue that the amount of punitive damages awarded was excessive.

Affirmed.